

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, April 6, 2009, 1:00 pm – 2:00 pm ET

Call Summary

I. Welcome and Introductions

In order to improve call management, calls will begin promptly at 1:00 pm ET. Roll call will be conducted by sending an email to Marcia Howard (mhoward@chpa-info.org) to indicate participation. After all agenda items have been addressed, anyone who joined late can be de-briefed about the prior discussion. Also, time will be allocated for each discussion topics in hopes of making the calls more efficient and ending a few minutes early so attendees can prepare for the next call or meeting.

Sub-team members are asked to share ideas about how to improve the teleconference process.

II. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or if you are listed and were not on the call) should contact Marcia.

-  Joan Berger, Image Solutions, Inc.
-  Cheryl Blik, Teva Pharmaceuticals, USA
-  Richard Brandt, Quark, Inc.
-  David Brown, Colgate Palmolive Company
-  Sue Crain, Watson Laboratories, Inc.
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Maureen Kapustynski, Cadbury
-  Mike Koenig, FDA
-  Juris Lazdins, Novartis Consumer Health, Inc.
-  Gayle Lempka, Watson Laboratories, Inc.

-  Paula Markert, GlaxoSmithKline Consumer Healthcare (sub-team co-leader)
-  Devon Morgan, Perrigo Company (sub-team co-leader)
-  Priscilla Mott, Johnson & Johnson Consumer & Personal Products Worldwide
-  Diane O'Grady, Purdue Pharma, L.P.
-  Janet Riffitts, McNeil Consumer Healthcare
-  Nick Romano, Novartis Consumer Healthcare
-  Gary Saner, Reed Technology and Information Services, Inc.
-  David Schilling, Chattem, Inc.
-  Howard Shatz, Data Conversion Laboratories, Inc.
-  Lonnie Smith, FDA
-  Siobhan Stevens-Miles, Merck & Co., Inc.
-  Carl Strotz, Wyeth Consumer Healthcare
-  Beth Thompson, Medline Industries, Inc.
-  Craig Trautman, Intagras
-  Mark Vranich, Blistex, Inc.
-  Ann Vu, FDA
-  Marcia Howard, CHPA staff (sub-team liaison)

III. Next Standing Teleconference: April 20, 2009, 1:00 – 2:00 pm ET (unless cancelled)

Please send any agenda topics to sub-team leaders Paula Markert (GSK), Devon Morgan (Perrigo), and sub-team liaison Marcia Howard (CHPA) at your convenience.

IV. FDA Data Council Issues

- A. **CORRECTION:** Posting of UNII Codes for Active (not inactive as originally stated on agenda) Ingredients for OTC Products

http://www.fda.gov/cder/Offices/OTC/OTC_ingredient_list_alphabetical_by_ingredient.pdf

The link provided does NOT contain UNII codes for active OTC ingredients. Companies should rely on any FDA list of UNII codes that has been made available to the public (e.g., XL spreadsheet) for acceptable UNII codes for SPL submissions.

- B. Two Common Errors with R4 Submissions

1. **SPL R4 documents submitted for the purpose of electronic drug establishment registration and drug listing without a folder.** As stated in section 5 of the *Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms v1.0* which was published in July 2008 with the draft guidance *Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing* "SPL files including all image files are placed in a folder and sent through the FDA Gateway."

If the SPL R4 file is submitted for the purpose of electronic drug establishment registration and drug listing without the folder via the OC gateway folder, the file will fail validation.

2. **Incorrect Gateway routing of SPL R4 electronic drug establishment registration and drug listing files and application submissions.** A few companies are utilizing the CDER or CBER gateway folders to submit SPL R4 eList submissions to FDA. If any gateway folder other than the "OC" folder is used to send in eList submissions, the file will not reach the appropriate center or office and will not be processed. If an eCTD file is submitted to "OC," it will not route to the appropriate center.






C. Updates to Data Council Web Pages (as of March 31, 2009)

1. Substance Registration System Web page
(<http://www.fda.gov/oc/datacouncil/SRS.htm>) – Updated to include link to UNII list with synonyms: <http://www.fda.gov/oc/datacouncil/UNIIs.zip>
2. SPL web page (<http://www.fda.gov/oc/datacouncil/spl.html>) – Updated to include links to:
 - a. UNII list with synonyms
(<http://www.fda.gov/oc/datacouncil/UNIIs.zip>)
 - b. XML terminology files with only preferred terms for substances and UNIIs (http://www.fda.gov/oc/datacouncil/terminology_lists.zip)
3. CDISC Data Standards Resources Web Page – Updated to provide additional details regarding the CDISC Content to Message Project
(<http://www.fda.gov/oc/datacouncil/cdisc.html>)
4. Standard for Exchange of Non-Clinical Data (SEND) Web Page – Updated to provide information regarding the SEND pilots and other details about SEND (<http://www.fda.gov/oc/datacouncil/send.html>)

V. Questions from Sub-team Members Regarding SPL

A. SPL Spreadsheet for Mass Delisting [see below for more information]

Companies should include the following information (at a minimum) to when submitting an Excel spreadsheet to the FDA for mass delisting:

-  Product name
-  NDC number
-  Product strength
-  Product unit
-  Discontinuation date

It is unclear how long it will take for products to be delisted in the NDC directory at this time.

B. June 1, 2009, Implementation Date

Today on the CDER website there was an announcement indicating that FDA will no longer accept paper submissions for Registration and Listing (<http://www.fda.gov/cder/index.html>). Companies must have any paper submissions **postmarked by May 31, 2009**, or they will be returned with directions on how to complete electronic submissions via the gateway.

C. Template of OTC Content of Labeling

FDA is in the process of drafting a representative template for OTC content of labeling (CoL) which will be distributed as soon as it is finalized.

D. Listing Information as Displayed on Daily Med

With release of R4, distributor/labeler information can be displayed on the Daily Med website depending on the information entered in the SPL file. Currently, R3 displays information for the company which captures the adverse event reports.

E. SPL Presentation at 2009 CHPA Regulatory & Scientific Conference (RSC)

Lonnie Smith (FDA) will be giving an update on SPL at the 2009 CHPA RSC. Sub-team members are asked to send key focus areas to Marcia Howard (CHPA) so that Lonnie can tailor his remarks accordingly to the extent possible. Space permitting, there may also be staff from the FDA who will be on site to provide information and answer questions about the upcoming implementation date for OTC electronic submissions. If confirmed, Marcia will let SPL OTC sub-team members know as soon as possible.

The RSC is open to the public. Program information, including registration details, can be found at <http://www.chpa-info.org/meetings/RSC.aspx>.

RSC Theme: **“Global Passport to Growth and Innovation”**

Dates: May 7-8, 2009 (Start time: 8:30 am ET both day; day 2 ends around 12:15 pm ET)

Location: Gaylord National Resort and Convention Center, National Harbor, MD (across the river from DC)

VI. Upcoming SPL Educational Forums

A. FDA face-to-face meeting on June 10, 2009, (attendance will be limited to available seats – seats are still available)

B. DIA SPL Workshop (Date and Location TBD; tentatively August 2009, in Philadelphia, PA)

Sub-team members are asked to send Devon, Paula, and Marcia recommendations for meeting topics for planning team consideration.

C. Others???

Sub-team members are encouraged to share educational opportunities that might be of interest to the group.

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Last Revised: April 6, 2009 Sent: April 6, 2009

Mass Delisting Procedures – From Generics SPL Sub-team Minutes of December 15, 2008

(Please visit Wiki page for additional information)

How to mass delist prior to the date when the electronic submission of drug establishment registration and drug listing information is mandatory.

This discussion is about NDC delisting. This would be to clean up NDC lists and avoid having to submit the SPL just to have it removed.

The information the FDA needs is:

- Name of drug
- Strength & unit
- Discontinuation date (may be future dated)
- NDC Number

The above is sufficient to remove NDC numbers from the NDC database. You may put in an Excel spreadsheet with the above information and send it to: spl@fda.hhs.gov prior to June 1, 2009 [**UPDATE**: FDA will continue to accept deletions via this procedure after June 1st.]